What is the translation of HSCL-25 in Italian: a consensus procedure by Delphi-round and Forward-Backward translation

Angélique Le Guennec

UNIVERSITÉ DE BREST - BRETAGNE OCCIDENTALE
Faculté de Médecine & des Sciences de la Santé

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Par **Mme LE GUENNEC Angélique**
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Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux.

Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J’interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l’humanité.

J’informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences.
Je ne tromperai jamais leur confiance et n’exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.
Je donnerai mes soins à l’indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

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List of Abbreviations

DSM IV: Diagnostic and Statistical Manual of Mental Disorders, fourth edition

EGPRN: European General Practice Research Network

FP: Family Practice

FPs: Family Physicians

FPDM: Family Practice Depression and Multimorbidity

HSCL-25: Hopkins Symptom Checklist in 25 items

NI: National Investigators

PT: Pilot Team

RAND/UCLA: Research ANd Development corporation and the University of California Los Angeles

HSCL-25 Forward-Backward translation to Italian by Delphi Procedure

Third Phase of FPDM

Résumé

Introduction : La dépression est une maladie chronique souvent diagnostiquée et traitée en soins primaires. La multimorbidité chez les patients de plus de 50 ans en est un facteur de risque important. Les variations interindividuelles et interculturelles rendent le diagnostic difficile. Peu d'outils diagnostics sont adaptés et utilisés par les médecins généralistes.

L'étude Family Practice Depression and Multimorbidity (FPDM) de l'European General Practice Research Network (EGPRN) souhaite valider un outil diagnostic de la dépression en médecine générale pour entreprendre des recherches européennes. Les deux premières étapes ont sélectionné la Hopkins Symptom Checklist en 25 items (HSCL-25) comme la plus appropriée selon les critères d'efficacité, de reproductibilité et d'ergonomie.

Objectif : L'objectif était de traduire la HSCL-25 en italien tout en adaptant son contenu aux particularités culturelles et linguistiques italiennes, sans perte de sens.

Méthode : Une procédure Delphi adaptée avec traduction aller-retour a été utilisée. Une traduction de l'anglais à l'italien a été soumise à un panel d'experts italiens en soins primaires. La traduction retour a été réalisée en aveugle de la version originale.

Résultats : Le panel d'experts répond aux critères d'inclusion. La traduction italienne a été validée au second tour. La traduction retour en anglais a été réalisée et acceptée par le comité scientifique de l'étude FPDM.

Discussion : Le choix d'une méthode de traduction aller-retour par procédure Delphi adaptée, avec exigence sur la qualité du panel d'experts, garantit une traduction italienne de HSCL-25 proche de l'original en terme de fiabilité et de validité. Une première analyse de la traduction retour (Depression Workshop Barcelona 2014) a mis en évidence des légères différences entre la version originale et la traduction retour. Prochainement, une analyse culturelle de la traduction assurera la concordance entre la version originale et la traduction retour.

Abstract

Introduction: Family physicians (FPs) are the first port of call for depressive patients in developed countries. Multimorbidity in patients over 50 years is an important risk factor for depression. Symptoms are difficult to identify owing to their inter-individual and intercultural variations. Few diagnostics tools are adapted and used by FPs. Family Practice Depression and Multimorbidity (FPDM) is a study managed by European General Practice Research Network (EGPRN). FPDM aims to find a diagnostic depression tool in primary care for collaborative research throughout Europe.

Previous steps of FPDM have found that the Hopkins Symptom Checklist in 25 items (HSCL-25) was the most appropriate tool according to the criteria of effectiveness, reproducibility and ergonomics.

Objective: To translate HSCL-25 in Italian while adapting its content to the cultural and linguistic characteristics ensuring that original meaning was preserved.

Method: A Delphi method adapted for a Forward-Backward translation was used. The translation from English to Italian was submitted to a panel of Italian experts in primary care. Backward translation was performed with a blind back-translation principle.

Results: The inclusion criteria of panel were followed. The Italian translation was confirmed in two Delphi rounds. The Backward English translation was produced and agreed by the FPDM's scientific committee.

Discussion: The Delphi method and the quality of the panel of experts FPs ensured a reliable Italian translation. A first analysis of the Backward translation (Depression Workshop Barcelona 2014) has highlighted the need for little changes between original and English backward version. The following step will consist in a cultural check to ensure that HSCL-25 is in total agreement with the Backward translation.

Introduction

Depression is the second most common chronic disorder seen by Family Physicians (FPs). FPs are the first port of call in most European Countries.[1] Multi-morbid patients over 50 years are especially at risk to develop a depression.[2-6] Depression is a variable combination of symptoms shared with other mental disorders like contextual distress, anxiety and somatoform disorders. The patient himself experiences difficulties to express his suffering and shows his own illness expression.[7]

The difficulties to diagnose and assess the severity of depression lie in this inter-individual variability. Clinicians often overestimate or underestimate the distress level of their patients.[8,9] Those difficulties may lead to inappropriate care and causes public health problems.[10] Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) is widely considered as gold standard to diagnose depression, but it's rarely used in Family practice.[11,12] Despite all this, Family Physicians (FPs) seem to be uncomfortable with depression definition and available diagnostic tools.[13,14] Incidence and prevalence rates of depression differ in Family Practice across Europe, related to complex contextual variations with differences in health care system, in concepts, objectives and practices as well as cultural variations in the expression of the disease.[15-18]

European FPs community needs a better knowledge of usable instruments to diagnose depression in adult patients.[8] There is also a need for a European consensus on a single diagnostic tool for depression to undertake collaborative research in Family practice throughout Europe.[19] This tool should be reliable, reproducible and ergonomic for FPs daily practice.

The Family Practice Depression and Multi-morbidity study (FPDM) started in 2011. The first and the second step highlighted the HSCL-25 as the best possible tool. This screening instrument was easy to implement and was extensively compared to DSM-IV. The HSCL-25 was used but there is no official and consensual translation available to most European languages.

Background

The aim of FPDM study was to select a single tool that could be consensually used by FPs to diagnose adult patient's depression and to make it applicable in the participating European countries. In order to be satisfactory, it had to be validated, reliable and easy to use by FPs throughout Europe; this study consisted of four steps.

The first step was a systematic literature review in order to select the candidate tools. This systematic review investigated all diagnosis tools that were validated for depression versus DSM-IV, in adult patients excluding pregnant and post-partum women. At the end of this step, seven tools were selected.[20]

The second step was a consensus procedure aiming to select a single tool among the seven candidates. The method chosen to reach a consensus was RAND/UCLA (Research ANd Development corporation and the University of California Los Angeles) procedure.[21] HSCL-25 was designated to be the most appropriate tool for depression diagnostic in adult patients in Family Practice throughout Europe, according to its criteria combined of reliability, reproducibility and ergonomics.

The third step consisted in translating this tool in the language of every country taking part in FPDM study, following the same consensus method, with the support of the European General Practice Research Network (EGPRN).
The difficulty is to achieve different language versions of the English instrument that are conceptually equivalent in each of the target countries. The focus is on cross-cultural and conceptual, rather than on linguistic or literal equivalence.[42]

The aim of this study was to translate HSCL-25 in Italian by using a Delphi consensus procedure with a Forward-Backward translation.

Method

Definition

The HSCL-25 is a self-report questionnaire on the existence and severity of both anxiety and depression symptoms during the previous week, used to identify psychiatric illness in primary care. It includes 25 items: 10 items about anxiety and 15 about depression.[22-24] The patient is considered as a “probable psychiatric case” if the mean rating on the HSCL-25 is ≥ 1,55. A cut-off value of ≥ 1,75 is generally used for diagnosis of major depression defined as “a case, in need of treatment”.[25,26] The HSCL-25 was used in family planning services, among refuges and among migrants.[27-29]

For the translation, to retain the same meaning as the original, a Forward-Backward translation was conducted following a consensus method: Delphi round. Consensus is the most appropriate method when there is a need to reach a solid consensus on a poorly investigated subject. Delphi procedure is used frequently in health care as a reliable and efficient way to reach consensus in defined clinical areas.[30-32] It is a systematic interactive method which involves a panel of experts using iterative procedures. It can be done quickly to make a convergent final recommendation. This process requires to follow four rules: anonymity of participants (ensures responses reliability and avoids contamination), iteration (allows participants to refine their views in the light of the progress of the group's work), control feedback (under the responsibility of a national investigator (NI)), statistical aggregation of group’s responses to allow a quantitative and qualitative analysis of the data.[33]

Consents and anonymity

The NI asked the participants for their signed consent, anonymized the expert responses and delivered an identification number.[21] The name of each expert was not transmitted to other. Only NI’s consent was sent to the investigator team. As the study involved no patient, it didn’t require an ethics committee‘s decision.

Participants

Pilot Team (PT): The EGPRN French team was familiar with Delphi methodology. It requested to the National Investigator his consent and voluntary participation in the study and an absence of conflict of interest. She/he ensured that

the whole process followed the protocol. It didn't take part in the translation phases or in Delphi rounds. The Forward-Backward translation had to be validated by the daily board of the study, composed of members of EGPRN all active within the research process.

National Investigator (NI): The NI was in charge of recruiting translators and experts. He acted between each phase and between two Delphi rounds. She/he did not act when a Delphi round was running.

Translators: The NI selected four translators to make up two translation teams. Translators had to be knowledgeable about health care terminology. The Forward translation team involved one member of the Family Physicians research group and one official translator. Italian had to be their native language. The Backward translation team involved one (or two) FP(s) and one official Italian/English translator.[34] The two teams should not have involved the same person.[35]

Experts panel: Initially, 20 to 30 experts were recruited in order to keep at least 15 participants until every round's end. The selection criteria for every expert were: being native to Italy and Italian was his native language; being English speaker; being in FP practice. Over half had to have teaching or research activities. In order to assess the representativeness of the panel by its diversity, the experts informed their gender, area of practice, years of practice and publications.[36]

Forward translation

The PT sent the HSCL-25 original English version to the NI who sent it to the Forward translation team. This team translated HSCL-25 from English to Italian aiming to retain the same meaning as the original.

Delphi rounds

At the beginning of the first round, NI sent by mail the original English version and a first translated version in Italian. FPs experts received records individually. NI did not use mailing list in order to assure anonymity which increased responses reliability and to avoid contamination (discussion between experts and leader's effect).[37]

Experts expressed their level of agreement on each proposal by using a Likert scale on each sentence of the translation. This Likert scale was an agree/disagree scale of 1 to 9 that measured the intensity of their agreement on each proposal. It took into account the maintenance of the meaning between the original and the translation

proposal, the ergonomics and the ease of understanding. Experts rated the proposal from 1 (absolutely no agreement) to 9 (fully agreement) and had to comment when rating less than 7. They were not aware of the following interpretation of data processing. Consensus was defined for a translation when it was rated 7 or above by over 70% of the panel, so it was accepted directly and did not enter the following rounds; if not (proposal didn‘t reach consensus), the NI and the Forward official translator synthesized experts comments to propose a new translation proposal for each sentence. Time between two rounds had to be less than 4 weeks. The following round began when the NI sent to the experts separately for each excerpt that didn’t reach consensus: the original English version, the unaccepted proposal, all the experts’ commented on this proposal, the new proposal. Experts rated the new proposal in the same way as for the first round. The following rounds rolled out in an identical manner. This process was repeated until all excerpts find a consensual translation. The number of rounds was not limited.[38]

At the Delphi procedure end, there was a consensus on a complete Italian version of HSCL-25.

Backward translation

NI sent the final Italian version of HSCL-25 to the Backward translation team who had to translate it into English. The translators should not have the knowledge of the original version (blind-back translation principle). Finally, he sent the Backward English version to the PT.[39]

Results

Forward translation

The NI submitted the questionnaire to one official translator and one FP researcher. A consensual Forward translation of HSCL-25 was proposed. (Tables 2 and 3) The native language of translators was Italian and they were knowledgeable about health care terminology.

Panel

The NI had particularly sought to obtain the consents of experts as well as the characteristics of each (Table 1). Eighteen FPs were recruited for the Delphi procedure. They were all FPs in Family Practice.

The panel for the second round was the same, but for one person who was left out due to serious health conditions.

The experts consisted of 67% male and 33% female. Their age was distributed as follows: Between 31-40 (39%); 41-50 (11%); 51-60 (17%); 61-70 (33%).

Experts worked in a city > 5000 (72%), in a small city (11%) and in a rural city (17%).

The expert's level of English was evaluated. Among the 18 FPs, 6% had an elementary level, 11% had an intermediary level, 33% had a superior intermediary level, 22% had an advanced level and 28% had a level of mastery of the language in complex situation.

Clinical experience was analysed by years of practice activity: 0-10 (44%); 11-20 (11%); 21-30 (28%); 31-40 (17%).

Among the 18 FPs experts, 61 % were academic researchers and had publications, 72% had a teaching activity. The others worked in general medical practice.

Delphi procedure

The first round (including the translation phase) was carried out between 8th August 2013 and 22nd April 2014. The second round started on 26th April 2014 and was completed on 6th August 2014.

The NI oversaw but didn't take part of the rounds. The NI had also conformed to the procedure of the Delphi round: the proposed translation was sent sentence by sentence to the experts, using a Likert scale in 9 points, in separated mails. There were two Delphi rounds to validate the Italian Forward translation of HSCL-25.

Five proposals were not accepted at the first round (3; 6; 12; 27; 28). Indeed, only 61% of the panel agreed with proposal 27 and 67% with proposals 3; 6; 12; 28.
These proposals were accepted at the second round: just one participant made a comment regarding the third item: “sentirsi intimoriti, mi sembrerebbe meglio” that is “sentirsi intimoriti, seems to me better”.

Backward translation

The Italian version obtained was translated in English by two independents translators, which gave us one Backward blind translation. The native language of the second translator was Italian and he was knowledgeable about health care terminology.

Table 1: Panel of FPs experts

FPs Experts Number	Gender	Age	English speaker	Practice activity (years)	Academic teachers (years)	Academic researcher (years)	Publication	Area of practice
	M: male		*(*)*				*Y - Yes*	*1. < 2000*
	F: female						*N - Not*	*2. 2000-5000*
								3. > 5000
1	F	37	C2	7	0	0	Y	3
2	M	34	B2	6	5	0	Y	3
3	M	56	C2	30	15	15	Y	1
4	M	61	B2	30	22	12	N	3
5	F	41	C1	3	0	0	N	2
6	M	35	B2	2	1	0	Y	2
7	M	61	B1	33	24	30	Y	3
8	M	64	C2	37	24	15	Y	3
9	M	53	C2	20	15	20	Y	3
10	F	36	B2	3	0	0	N	3
11	F	34	B1	1	1	2	Y	3
12	M	38	B2	3	0	0	N	3
13	F	49	C1	17	15	10	N	1
14	F	34	C1	1	0	0	N	1
15	M	61	B2	35	12	12	Y	3
16	M	61	A2	30	14	5	Y	3
17	M	65	C2	30	18	22	Y	3
18	M	54	C1	21	12	15	Y	3

(*) A1 = Level base; A2 = Elementary level ;B1 = Intermediary Level or "threshold"; B2 = Superior intermediary level 5; C1 = Advanced level or "autonomous efficiency"; C2 = Level of mastery of the language in complex situations

Table 2: HSCL-25: First Round; Original version/ Forward version/ Backward version

	ORIGINAL ENGLISH VERSION	FORWARD	BACKWARD
1*	Choose the best answer for how you felt over the past week	Scegliere la risposta più adatta su come ti sei sentito nell'ultima settimana	Choose the answer that best describes how you have been feeling during the past week
2*	Being scared for no reason	Avere paura senza motivo	Being afraid with no reason
3	Feeling fearful	Essere timorosi	Feeling fearful
4	Faintness	Sensazione di mancamento	Faintness
5*	Nervousness	Essere nervoso	Feeling nervous
6*	Heart racing	Avere tachicardia	Tachycardia
7	Trembling	Tremore	Trembling
8	Feeling tense	Sensazione de tensione	Feeling tense
9*	Headache	Avere mal di testa	Experiencing headache
10*	Feeling panic	Sensazione di panico	Panicky
11	Feeling restless	Sensazione de irrequietezza	Feeling restless
12*	Feeling low in energy	Sentirsi stanco	Feeling tired
13	Blaming oneself	Avere sensi di colpa	Blaming oneself
14*	Crying easily	Piangere facilmente	Often tearful
15	Losing sexual interest	Perdere l'interesse sessuale	Losing sexual interest
16	Feeling lonely	Sentirsi soli	Feeling lonely
17*	Feeling hopeless	Sentirsi senza speranza	Without hope
18*	Feeling blue	Sentirsi tristi	Feeling sad
19*	Thinking of ending one's life	Avere pensieri di togliersi la vita	Thinking about taking one's life
20	Feeling trapped	Sentirsi intrapollati	Feeling trapped
21	Worrying too much	Preoccuparsi troppo	Worrying too much
22*	Feeling no interest	Non avere alcun interesse	No interest in anything
23	Feeling that everything is an effort	Sentire che tutto è uno sforzo	Feeling that everything is an effort
24*	Worthless feeling	Sentirsi inutile	Feeling of uselessness
25*	Poor appetite	Avere poco appetito	Loss of appetite
26	Sleep disturbance	Disturbu del sonno	Sleep disturbance

ORIGINAL ENGLISH VERSION	**27*.** The HSCL-25 score is based on pencil-and-paper self-report of 25 questions about the presence and intensity of anxiety and depression symptoms over the last week. Participants answer to one of four categories for each item on a four-point scale ranging from 1 to 4.			
	28*."Not at all"	**29***."A little"	**30***."Quite a bit"	**31***."Extremely"
	32*. The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1,00 and 4,00). It is often used as the measure of distress. The patient is considered as a "*probable psychiatric case"* if the mean rating on the HSCL-25 is ≥ 1,55. A cut-off value of ≥ 1,75 is generally used for diagnosis of major depression defined as "*a case, in need of treatment"*. This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender. The administration time of HSCL-25 is 5 to 10 minutes.			
FORWARD	**27***. Il punteggio dell'HSCL-25 si basa su un'autovalutazione in carta e penna di 25 domande sulla presenza e intensità sui sintomi di ansia e depressione nell'ultima settimana. I partecipanti rispondono a una delle quattro categorie per ogni elemento in una scala di 4 punti che si estende da 1 a 4.			
	28*. Niente	**29***. Poco	**30***. Abbastanza	**31***. Moltissimo
	32*. Il punteggio dell'HSCL-25 si calcola dividendo il punteggio totale (somma dei punteggi degli elementi) con il numero di elementi risposti (che variano da 1,00 a 4,00). Spesso si usa come misura di ansietà. Il paziente è considerato come un "probabile caso psichiatrico" se il punteggio medio dell'HSCL-25 è ≥1,55. Un cut-off che sia ≥ 1,75 è normalmente usato per la diagnosi di depressione maggiore definita come "un caso che necessita di trattamento". Questo cut-off è raccomandato come un valido predittore di disordine mentale come valutato in modo indipendente da un colloquio clinico, dipendente in qualche modo dalla diagnosi e dal genere. Il tempo di somministrazione dell'HSCL-25 è da 5 a 10 minuti.			
BACKWARD	**27***.The HSCL-25 score is based on a self - assessment on pen and paper of 25 questions regarding the presence and intensity of the symptoms of anxiety and depression during the last week. The participants reply to one of the four categories for every item on a scale of 4 points which ranges from 1 to 4.			
	28*. Nothing	**29***. Slightly	**30***. Significantly	**31***. Very much
	32*. The HSCL-25 score is calculated by dividing the total score (the sum of the scores of the items) by the number of items replied to (which vary from 1.00 to 4.00). It is often used to measure anxiety. The patient is considered to be a "likely psychiatric case" if the average score of the HSCL-25 is ≥ 1.55. A cut-off point of ≥ 1.75 is normally used for the diagnosis of worse depression defined as "a case that requires treatment". This cut-off is recommended as a reliable predictor of mental disorder as evaluated independently via a clinical discussion, dependent in part on the diagnosis and the type. The HSCL-25 takes between 5 and 10 minutes to complete.			

**: backward translation different from original english version coloured cells: not accepted at the first round*

Table 3: Final Forward and Backward translation after the second round

	ORIGINAL ENGLISH VERSION	FORWARD	BACKWARD
1*	Choose the best answer for how you felt over the past week	Scegliere la risposta più adatta su come ti sei sentito nell'ultima settimana	Choose the answer that best describes how you have been feeling during the past week
2*	Being scared for no reason	Avere paura senza motivo	Being afraid with no reason
3	Feeling fearful	Sentirsi impauriti	Feeling fearful
4	Faintness	Sensazione di mancamento	Faintness
5*	Nervousness	Essere nervoso	Feeling nervous
6*	Heart racing	Sentire il cuore battere veloce	Feeling your heart beating fast
7	Trembling	Tremore	Trembling
8	Feeling tense	Sensazione de tensione	Feeling tense
9*	Headache	Avere mal di testa	Experiencing headache
10*	Feeling panic	Sensazione di panico	Panicky
11	Feeling restless	Sensazione de irrequietezza	Feeling restless
12*	Feeling low in energy	Sentirsi senza energia	Feeling drained of energy
13	Blaming oneself	Avere sensi di colpa	Blaming oneself
14*	Crying easily	Piangere facilmente	Often tearful
15	Losing sexual interest	Perdere l'interesse sessuale	Losing sexual interest
16	Feeling lonely	Sentirsi soli	Feeling lonely
17*	Feeling hopeless	Sentirsi senza speranza	Without hope
18*	Feeling blue	Sentirsi tristi	Feeling sad
19*	Thinking of ending one's life	Avere pensieri di togliersi la vita	Thinking about taking one's life
20	Feeling trapped	Sentirsi intrapollati	Feeling trapped
21	Worrying too much	Preoccuparsi troppo	Worrying too much
22*	Feeling no interest	Non avere alcun interesse	No interest in anything
23	Feeling that everything is an effort	Sentire che tutto è uno sforzo	Feeling that everything is an effort
24*	Worthless feeling	Sentirsi inutile	Feeling of uselessness
25*	Poor appetite	Avere poco appetito	Loss of appetite
26	Sleep disturbance	Disturbu del sonno	Sleep disturbance

ORIGINAL ENGLISH VERSION	**27*.** The HSCL-25 score is based on pencil-and-paper self-report of 25 questions about the presence and intensity of anxiety and depression symptoms over the last week. Participants answer to one of four categories for each item on a four-point scale ranging from 1 to 4.			
	28*."Not at all"	**29***."A little"	**30***."Quite a bit"	**31***."Extremely"
	32*. The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1,00 and 4,00). It is often used as the measure of distress. The patient is considered as a "*probable psychiatric case"* if the mean rating on the HSCL-25 is ≥ 1,55. A cut-off value of ≥ 1,75 is generally used for diagnosis of major depression defined as "*a case, in need of treatment"*. This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender. The administration time of HSCL-25 is 5 to 10 minutes.			
FORWARD	**27***. Il punteggio dell'HSCL-25 si basa sulla compilazione di un questionario di autovalutazione in cartaceo ("carta/penna") di 25 domande sulla presenza e intensità di sintomi di ansia e depressione nel corso dell'ultima settimana. I partecipanti rispondono ad una delle quattro categorie per ciascun sintomo su una scala di punteggio che va da 1 a 4.			
	28*. Per niente	**29***. Poco	**30***. Abbastanza	**31***. Moltissimo
	32*. Il punteggio dell'HSCL-25 si calcola dividendo il punteggio totale (somma dei punteggi degli elementi) con il numero di elementi risposti (che variano da 1,00 a 4,00). Spesso si usa come misura di ansietà. Il paziente è considerato come un "probabile caso psichiatrico" se il punteggio medio dell'HSCL-25 è ≥1,55. Un cut-off che sia ≥ 1,75 è normalmente usato per la diagnosi di depressione maggiore definita come "un caso che necessita di trattamento". Questo cut-off è raccomandato come un valido predittore di disordine mentale come valutato in modo indipendente da un colloquio clinico, dipendente in qualche modo dalla diagnosi e dal genere. Il tempo di somministrazione dell'HSCL-25 è da 5 a 10 minuti.			
BACKWARD	**27***. The HSCL-25 score is based on the compilation of a self - assessment paper questionnaire ("pen/paper") of 25 questions regarding the presence and intensity of the symptoms of anxiety and depression during the last week. The participants reply to one of the four categories for every symptom on a scale which ranges from 1 to 4.			
	28*. By no means	**29***. Slightly	**30***. Significantly	**31***. Very much
	32*. The HSCL-25 score is calculated by dividing the total score (the sum of the scores of the items) by the number of items replied to (which vary from 1.00 to 4.00). It is often used to measure anxiety. The patient is considered to be a "likely psychiatric case" if the average score of the HSCL-25 is ≥ 1.55. A cut-off point of ≥ 1.75 is normally used for the diagnosis of worse depression defined as "a case that requires treatment". This cut-off is recommended as a reliable predictor of mental disorder as evaluated independently via a clinical discussion, dependent in part on the diagnosis and the type. The HSCL-25 takes between 5 and 10 minutes to complete.			

Discussion

There were two Delphi rounds, led between August 2013 and August 2014, to validate the Italian Forward translation of HSCL-25. This version was translated in English by two independents translators to obtain a Backward blind translation.

The power of the study was based on its methodology and the selection of FPs experts.[40-41] The Delphi procedure with FPs experts aimed to evaluate the Italian's translation and integrate idiomatic expressions, colloquial health phrase and emotional terms in daily use. The procedure allowed to evaluate a question quickly and cheaply without geographical constraints. The Likert scale is an international validated, qualitative and ordinal scale. The ranking 7 or above guaranteed an adherence to the translation.

Selection bias & sample's characteristics

The sample's characteristics are always disputable. First of all, they were carefully chosen to ensure a maximum of heterogeneity of the panel. All types of FPs were represented. FPs experts were sufficient (18 FPs) according to Delphi procedure. Experts were native of Italy and Italian was their native language. Each expert was competent in English. The translation's judgment was provided by a mix of academic and non-academic FPs. This result has to commented: only 28% are not academic FPs (neither teacher nor researcher). It seems justifiable to think that the fact of selecting professionals with a good level of English explains the over-representation of academic FPs. Moreover, a consequence of the academic criterion was reflected with a majority in City (>5000) practice. To ensure homogeneity of the Italian translation through Italy, the NI had selected FPs experts who came from different geographical locations.

The panel was the same for the two rounds, but for one person who was left out due to serious health conditions. The number of experts remaining upper to 15, it does not seem that it can have of significant repercussions on the final results.

Sample was defined according to gender, age and area of practice. Long years of practice ensured the relevance of evaluations. There was no selection bias according to sample's characteristics

Information bias

As the NI organized the Delphi round according to protocol: the proposed translation was sent sentence by sentence to the experts. No information bias was possible as every participant had a full access to the whole data.

Confusion bias

Forward-Backward is an international consensual process of translation and adaptation of instruments. The Forward translation process aimed to respect the faithfulness of meaning in English and Italian. A specific attention was paid to choose FP researcher and certified bilingual translator knowledgeable about health care terminology. To ensure homogeneity, a Backward translation was necessary. The backward translator was working blind and was an academic official translator.[42,43]
The second round began 4 days after the end of the first round, according to the protocol.
Each expert expressed his judgment individually and anonymously. The lack of face-to-face meeting avoided the “opinion leader” effect and limits conflicts of interest.
All those arguments reduced the confusion bias, which is, however, never null with this type of method.

Comments

The choice of words was essential to keep the meaning of items. There were differences in words and syntax between original English version of HSCL-25 and Backward translation.
Concerning the backward translation resulting from the first round, the meaning could be qualified has stronger for 6 proposals: 2 (scared / *“paura”* / afraid); 10 (feeling panic / *“sensazione di panico”* / panicky); 18 (blue / *“tristi”* / sad); 25 (poor appetite / *“avere poco appetito”* / loss of appetite); 30 (quite a bit / *“abbastanza”* / stronger); 32 (distress / *“ansieta”* / anxiety).
Two could have a different meaning: 24 (worthless / *“inutile”* / uselessness); 32 (valid / *“valido”* / reliable, and gender / *“genere”* / type).
A cultural check will examine these changes.[44-46]

Conclusion

The third phase of FPDM, using a Delphi procedure and Forward-Backward translation, allowed the translation of HSCL-25 in Italian. The translation realized in Italy obtained a consensus with two Delphi rounds. The translation analysis was performed by official translators and a panel of FPs experts. A mix of FPs experts was selected according to specific criteria (language skills, academic activities, teaching activities, experience, area of practice, gender and age). The result is a fully translated HSCL-25 in Italian language.

The cross-cultural approach is complex. The reliability of HSCL-25's using depended to an acute translation. It must integrate understanding of a socio-cultural and linguistic background. This methodological approach was focused on translation, adaptation and cross-validation of HSCL-25 in Italian. A cultural check will verify their validity, ensuring that the meaning of every translation remains the same compared to the original English version.

With all translations, collaborative research in primary care in Italy and throughout Europe will be undertaken. This will allow a reliable comparison of the diagnostic assessment of depression and treatment practices between different European countries. The FPs can exchange more objectively with healthcare authorities and psychiatrists on the prevalence, incidence and treatment of depression in primary care.

The fourth step of FPDM will consist in testing the HSCL-25 in each language in order to assess the reliability, reproducibility and ergonomics of the tool in practice.

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Annex 1: Panel Results for the first round

	FP's experts	1	2	3	3	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Item HSCL-25																			
1		6	6	9	9	9	9	8	7	7	9	8	9	9	8	7	9	9	9
2		7	6	9	9	8	9	9	8	8	9	9	9	9	9	8	9	8	9
3		2	4	7	6	5	6	7	8	8	6	7	8	7	8	8	8	8	8
4		7	6	8	9	8	9	9	8	9	9	9	8	9	9	8	7	9	8
5		8	7	8	6	8	9	9	8	8	9	8	7	9	9	6	7	7	8
6		8	6	9	5	5	6	7	8	8	9	6	7	9	9	8	8	9	6
7		8	7	9	9	8	9	9	8	9	8	9	9	9	9	9	8	9	8
8		4	7	9	9	9	9	9	8	9	8	8	8	9	9	8	8	9	9
9		7	7	9	9	9	9	9	8	9	9	9	9	9	9	5	7	8	8
10		8	7	9	5	9	9	9	8	9	9	9	9	9	9	8	9	9	9
11		6	7	9	9	9	9	9	8	9	9	9	9	9	9	8	9	9	9
12		8	7	5	6	5	9	7	8	8	8	6	9	6	9	6	9	8	8
13		8	6	9	9	9	9	9	8	9	8	9	9	9	9	4	9	9	9
14		8	7	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9
15		8	6	9	5	9	6	8	8	7	9	7	9	9	9	8	9	9	9
16		8	7	9	6	9	9	9	8	9	9	9	9	9	9	9	9	9	9
17		8	7	9	9	9	9	9	8	9	9	9	9	9	9	7	9	9	9
18		8	7	7	6	8	9	9	8	9	9	9	9	9	9	8	9	9	9
19		6	6	9	6	8	9	6	8	9	9	7	7	9	9	7	9	9	9
20		9	6	9	6	8	9	9	8	9	9	6	9	9	9	9	9	9	9
21		9	6	9	9	8	9	9	8	9	9	9	9	9	9	9	8	9	9
22		8	6	9	9	8	9	9	8	7	9	9	8	9	9	9	9	9	9
23		9	6	5	5	8	9	9	8	9	9	9	9	9	9	8	8	9	8
24		9	7	9	9	9	9	9	8	9	9	9	9	6	9	9	9	9	9
25		9	7	9	6	9	9	9	8	9	9	9	9	9	9	5	8	9	9
26		8	7	9	6	9	9	9	8	9	9	9	9	9	9	9	8	9	9
27		3	6	9	9	8	6	6	8	8	9	6	6	9	9	4	8	9	9
28		3	6	9	9	8	9	4	8	8	6	8	9	5	9	7	9	6	7
29		8	7	9	9	8	9	9	8	9	9	9	8	9	9	9	9	8	8
30		6	7	9	9	8	9	8	8	9	9	9	9	9	9	9	9	9	9
31		8	7	9	9	8	9	8	8	9	6	9	9	9	9	8	9	9	9
32		3	6	8	8	8	6	5	8	8	9	8	8	8	8	4	8	8	9

Legend:

- Not accepted proposals
- Note between 1 and 3
- Note beetween 4 and 6

Annex 2: HSCL-25 Hopkins Symptom Checklist

Département Universitaire de Médecine Générale

22, avenue Camille Desmoulins CS 93837 – 29238 – Brest CEDEX 3
Tél : 02 98 01 65 52 – fax : 02 98 01 64 74

Choose the best answer for how you felt over the past week:

Items		1: “Not at all”	2:“A little”	3:Quite a bit”:	4: “Extremely”
1	Being scared for no reason				
2	Feeling fearful				
3	Faintness				
4	Nervousness				
5	Heart racing				
6	Trembling				
7	Feeling tense				
8	Headache				
9	Feeling panic				
10	Feeling restless				
11	Feeling low in energy				
12	Blaming oneself				
13	Crying easily				
14	Losing sexual interest				
15	Feeling lonely				
16	Feeling hopeless				
17	Feeling blue				
18	Thinking of ending one’s life				
19	Feeling trapped				
20	Worrying too much				
21	Feeling no interest				
22	Feeling that everything is an effort				
23	Worthless feeling				
23	Poor appetite				
25	Sleep disturbance				

The HSCL-25 score is calculated by dividing the total score (sum score of items) by the number of items answered (ranging between 1,00 and 4,00). It is often used as the measure of distress.
The patient is considered as a “probable psychiatric case” if the mean rating on the HSCL-25 is ≥ 1,55.
A cut-off value of ≥ 1,75 is generally used for diagnosis of major depression defined as “a case, in need of treatment”. This cut-off point is recommended as a valid predictor of mental disorder as assessed independently by clinical interview, somewhat depending on diagnosis and gender.
The administration time of HSCL-25 is 5 to 10 minutes.

Annex 3**:** informed consent (to translate in your language)

Département Universitaire de Médecine Générale

22, avenue Camille Desmoulins CS 93837 – 29238 – Brest CEDEX 3

Tél : 02 98 01 65 52 – fax : 02 98 01 64 74

INFORMATION NOTICE

International Investigator Senior Coordinator

Name: Nabbe Patrice

Address: Département de médecine générale, Faculté de Médecine de Brest, 22, avenue Camille Desmoulins, 29238 Brest cedex 3

International Developer

Département Universitaire de Médecine Générale – 22 avenue Camille Desmoulins - 29238 Brest Cedex 3

National investigator senior coordinator:

Name:
Address:
National developer:

Dear Madam or Sir

You are invited to participate in a survey by Le Guennec Angélique (trainee in general practice). The department of general practice from Brest is the national developer of that survey. He is responsible for it and assumes its organization.

Mrs/Mr …….. will explain his/her work to you. If you decide to participate you will be asked to sign a consent form. This signature will confirm that you did agree to participate.

1. **Course of study**

A Delphi procedure. This Delphi procedure will be fully anonymized and it will be impossible for a study reader to identify you.

2. **Potential risk of study**

There are no risks associated with your participation in this study

3. Potential benefits of the study

There is no potential benefit to this study

4. Voluntary participation

Your participation to this study is entirely voluntary.

You are free to refuse to participate and to terminate your participation in the study at any time and without incurring any liability or any injury of this fact and without causing consequences.

In this case you must inform the investigator of your decision

In the event that you withdraw your consent, we will conduct a computer processing of your personal data unless written objection on your part.

During the study, your investigator will notify you, if new facts might affect your willingness to participate in the study.

5. Obtaining complementary informations

If desired, Patrice Nabbe or local national investigator (phone number), who can be reached at telephone number: 00 33 298 835 131 or 00 33 607 631 490 at any time can answer all your questions about the study.

At the end of the study, and at your request, your investigator will inform you of the overall results of this research.

6. Confidentiality and use of medical or personal data

As part of biomedical research in which the DUMG Brest, Patrice Nabbe and your national investigator offer to participate, a treatment of your personal data will be used to analyse the results of research in light of the objective of that study which was presented to you.

To this end, the data collected, including any survey and the data on your lifestyle will be forwarded to the promoter of the research where the data will be processed in this study.

Those data will be anonymized and their identification will be held with a code number. Staff involved in the study is subject to professional secrecy. These data may also, under conditions ensuring their confidentiality be transmitted to the national or European health authorities.

Under the provisions of Law you have the right to access and modify. You also have the right to object to the transmission of data covered by professional secrecy.

If you agree to participate in this study, thank you to complete and sign the consent form. You will keep a copy of it.

Annex 4: Consent Form for each leader

Consent Form (for each leader with department of general practice, Brest, France

Promoter : Département Universitaire de Médecine Générale – 22 avenue Camille Desmoulins - 29238 Brest Cedex

Dr: NABBE Patrice

Address: Département de médecine générale, Faculté de Médecine de Brest, 22, avenue Camille Desmoulins, 29238 Brest cedex 3, FRANCE

National leader investigator name

Address: ……..

University:

Asked me to participate in a Forward-Backward translation.

I had time to reflect on my involvement in this study. I am aware that my participation is completely voluntary and that the study will entail no additional cost to my charge.

I can, at any time, decide to leave the study without giving reasons for my decision and that it does without consequences.

I understood that the data collected during the research would be protected in accordance to confidentiality. They can only be accessed by persons subject to professional secrecy belonging to the team-investigating physician, mandated by the promoter.

I accept the computerized processing of personal data in accordance with the data protection act. I have been informed of my right to access and rectify data concerning me.

My consent does not absolve the responsibilities of the organizers of this research. I retain all my rights guaranteed by Law.

Done in two originals

at……, the dd/mm/yyyy

Name, first name of national leader: Name, first name of the interviewee:

Signature:

Annex 5**:** Consent Form for each national team

Consent Form (for each national leader with each member of local national team)

Promoter : Département Universitaire de Médecine Générale – 22 avenue Camille Desmoulins - 29238 Brest Cedex 3

Dr:…….

Address:
……

Local investigator name

Address: ……..

University:

Asked me to participate in a Delphi consensus.

I had time to reflect on my involvement in this study. I am aware that my participation is completely voluntary and that the study will entail no additional cost to my charge.

I can, at any time, decide to leave the study without giving reasons for my decision and that it does without consequences.

I understood that the data collected during the research would be protected in accordance to confidentiality. They can only be accessed by persons subject to professional secrecy belonging to the team-investigating physician, mandated by the promoter.

I accept the computerized processing of personal data in accordance with the data protection act. I have been informed of my right to access and rectify data concerning me.

My consent does not absolve the responsibilities of the organizers of this research. I retain all my rights guaranteed by Law.

Done in two originals

at……, the dd/mm/yyyy

Name, first name of investigator: Name, first name of the interviewee:

Signature:

UNIVERSITE DE BREST - BRETAGNE OCCIDENTALE

Faculté de Médecine & des Sciences de la Santé

*****

AUTORISATION D'IMPRIMER

****

Présentée par :
M. le Professeur LE RESTE Jean-Yves

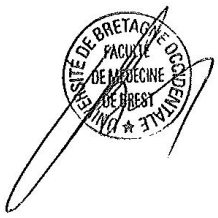
Titre de la thèse :
« What is the translation of HSCL-25 in Italian ; A consensus procedure by Delphi-round and Forward-Backward translation »

ACCORD DU PRESIDENT DU JURY DE THESE SUR L'IMPRESSION DE LA THESE

En foi de quoi la présente autorisation d'imprimer sa thèse est délivrée à :
Mme LE GUENNEC Angélique, Interne de Médecine Générale

Fait à BREST, le 14/08/*2014*

VISA du Doyen de la faculté
Professeur C. BERTHOU



Le Président du Jury de Thèse
Professeur JY. LE RESTE

Professeur J.Y. LE RESTE
Directeur du Département
Département de Médecine Générale

LE GUENNEC Angélique - *What is the translation of HSCL-25 in Italian; A consensus procedure by Delphi-round and Forward-Backward translation.*
37 pages, 3 tables, 5 annexes, Thèse Médecine: Brest 09/2014

RESUME / ABSTRACT

Introduction : La dépression est une maladie chronique souvent diagnostiquée et traitée en soins primaires. La multimorbidité chez les patients de plus de 50 ans en est un facteur de risque important. Les variations interindividuelles et interculturelles rendent le diagnostic difficile. Peu d'outils diagnostics sont adaptés et utilisés par les médecins généralistes.
L'étude Family Practice Depression and Multimorbidity (FPDM) de l'European General Practice Research Network (EGPRN) souhaite valider un outil diagnostic de la dépression en médecine générale pour entreprendre des recherches européennes. Les deux premières étapes ont sélectionné la Hopkins Symptom Checklist en 25 items (HSCL-25) comme la plus appropriée selon les critères d'efficacité, de reproductibilité et d'ergonomie.
Objectif : L'objectif était de traduire la HSCL-25 en italien tout en adaptant son contenu aux particularités culturelles et linguistiques italiennes, sans perte de sens.
Méthode : Une procédure Delphi adaptée avec traduction aller-retour a été utilisée. Une traduction de l'anglais à l'italien a été soumise à un panel d'experts italiens en soins primaires. La traduction retour a été réalisée en aveugle de la version originale.
Résultats : Le panel d'experts répond aux critères d'inclusion. La traduction italienne a été validée au second tour. La traduction retour en anglais a été réalisée et acceptée par le comité scientifique de l'étude FPDM.
Discussion : Le choix d'une méthode de traduction aller-retour par procédure Delphi adaptée avec exigence sur la qualité du panel d'experts, garantit une traduction italienne de HSCL-25 proche de l'original en terme de fiabilité et de validité. Une première analyse de la traduction retour (Depression Workshop Barcelona 2014) a mis en évidence des légères différences entre la version originale et la traduction retour. Prochainement, une analyse culturelle de la traduction assurera la concordance entre la version originale et la traduction retour.

Introduction: Family physicians (FPs) are the first port of call for depressive patients in developed countries. Multimorbidity in patients over 50 years is an important risk factor for depression. Symptoms are difficult to identify owing to their inter-individual and intercultural variations. Few diagnostics tools are adapted and used by FPs. Family Practice Depression and Multimorbidity (FPDM) is a study managed by European General Practice Research Network (EGPRN). FPDM aims to find a diagnostic depression tool in primary care for collaborative research throughout Europe.
Previous steps of FPDM have found that the Hopkins Symptom Checklist in 25 items (HSCL-25) was the most appropriate tool according to the criteria of effectiveness, reproducibility and ergonomics.
Objective: To translate HSCL-25 in Italian while adapting its content to the cultural and linguistic characteristics ensuring that original meaning was preserved.
Method: A Delphi method adapted for a Forward-Backward translation was used. The translation from English to Italian was submitted to a panel of Italian experts in primary care. Backward translation was performed with a blind back-translation principle.
Results: The inclusion criteria of panel were followed. The Italian translation was confirmed in two Delphi rounds. The Backward English translation was produced and agreed by the FPDM's scientific committee.
Discussion: The Delphi method and the quality of the panel of experts FPs ensured a reliable Italian translation. A first analysis of the Backward translation (Depression Workshop Barcelona 2014) has highlighted the need for little changes between original and English backward version. The following step will consist in a cultural check to ensure that HSCL-25 is in total agreement with the Backward translation.

MOTS CLES :

Depression / Translation / HSCL-25 / Delphi / Italian

JURY :

PRÉSIDENT DU JURY Pr. JY. LE RESTE

MEMBRES DU JURY Pr. B. LE FLOCH
Dr. P. NABBE

DATE DE SOUTENANCE :

Jeudi 11 Septembre 2014

ADRESSE DE L'AUTEUR :

320, rue Jim Sévellec
29800 LANDERNEAU
FRANCE